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ATTORNEY DOCKET NO. APPLICATION NO. **FILING DATE** FIRST NAMED INVENTOR 06/30/99 EMDI J P564-9014 09/343,406 **EXAMINER** HM22/1004 NIKAIDO MARMELSTEIN MURRAY & ORAM LLP DIBRINO, M METROPOLITAN SQUARE ART UNIT PAPER NUMBER 655 FIFTEENTH STREET N W SUITE 330 G STREET LOBBY 1644 WASHINGTON DC 20005-5701 DATE MAILED: 10/04/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No. **09/343,406**

Appl (s)

Endl

Examiner

Marianne DiBrino

Group Art Unit 1644

Responsive to communication(s) filed on	
☐ This action is FINAL .	
☐ Since this application is in condition for allowance except for formal matters, in accordance with the practice under Ex parte Quay#835 C.D. 11; 453 O.G. 213.	
A shortened statutory period for response to this action is set to expire	
Disposition of Claim	
X Claim(s) <u>1-24, 28-30, 35, 36, and 41-45</u> is/a	re pending in the applicat
Of the above, claim(s) is/are wit	hdrawn from consideration
☐ Claim(s)	_ is/are allowed.
☐ Claim(s)	is/are rejected.
☐ Claim(s)	·
X Claims <u>1-24, 28-30, 35, 36, and 41-45</u> are subject to restricti	on or election requirement.
Application Papers See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948. The drawing(s) filed on is/are objected to by the Examiner.	
☐ The proposed drawing correction, filed on is ☐ approved ☐ disapproved	oved.
☐ The specification is objected to by the Examiner.	
☐ The oath or declaration is objected to by the Examiner.	
Priority und r 35 U.S.C. § 119 Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d). All Some* None of the CERTIFIED copies of the priority documents have been received. received in Application No. (Series Code/Serial Number) received in this national stage application from the International Bureau (PCT Rule 17.2(a)). *Certified copies not received: Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).	
Attachm nt(s) Notice of References Cited, PTO-892 Information Disclosure Statement(s), PTO-1449, Paper No(s). Interview Summary, PTO-413 Notice of Draftsperson's Patent Drawing Review, PTO-948 Notice of Informal Patent Application, PTO-152	
SEE OFFICE ACTION ON THE FOLLOWING PAGES	

DETAILED ACTION

- 1. Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.
- 2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
- I. Claims 1-6 and 22-24 drawn to a peptide/peptide derivative, and compositions comprising said peptide/peptide derivative, classified in Class 530, subclass 328.
 - II. Claim 7, drawn to a peptide mimetic, classified in Class 536, subclass 123.1.
- III. Claims 8-21, drawn to a complex comprising a peptide or peptide derivative bound to an MHC molecule/derivative, and oligomers, thereof, classified in Class 530, subclass 350.
- IV. Claims 28-30 drawn to a method for determination of a specific T cell subpopulation, classified in Class 435, subclass 7.24.
- V. Claims 35 and 36, drawn to a method for the isolation of a specific T cell subpopulation, classified in Class 435, subclass 7.21.
 - VI. Claim 41, drawn to an antibody, classified in Class 530, subclass 387.9.
- VII. Claims 43-45, drawn to a T cell which reacts with a peptide, classified in Class 435, subclass 325.
- VIII. Claim 42, drawn to an anti-idiotypeic antibody, classified in Class 530, subclass 387.2.
- 3. Inventions I, II, III, VI VII and VIII are different products.

Peptides, peptide mimetics, complexes of protein and peptide, antibodies and T cells have different structures, properties and modes of action. Peptides are comprised of amino acid residues, peptide mimetics are nonpeptidic, complexes comprising protein are longer than peptides and have more secondary and tertiary structure, antibodies are molecules comprised of different proteins and bind specific antigens. The anti-idiotypic antibody of Group VIII is

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specific for the antibody of Group VI, and the antibody of Group VI is specific for a peptide, peptide derivative or mimetic or complex comprising said peptide.

4. Inventions IV and V are different methods.

These inventions require different ingredients and process steps to accomplish the use of either determining a specific T cell subpopulation or isolating a specific T cell subpopulation.

5. Inventions (I and II, products) and Inventions (IV and V) are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the product as claimed can be used in any of the two distinct processes of Inventions IV or V, or alternatively as an antigen for the production of antibodies.

- 6. Because these inventions are distinct for the reasons given above and the search required for any group from Groups I-VII is not required for any other group from Groups I-II and Groups I-V have acquired a separate status in the art as shown by their different classification (and the searches are not co-extensive) and divergent subject matter, restriction for examination purposes as indicated is proper.
- 7. If Applicant elects the Invention of Group I, II, III, VI, VII, or VIII, Applicant is further required to (1) elect a specific peptide, a specific peptide mimetic, a specific complex comprising a specific peptide and a specific MHC molecule, an antibody to a specific peptide/derivative or mimetic, a T cell that reacts with a specific peptide, or an anti-idiotypic antibody specific for an antibody which is specific for a specific peptide/derivative or mimetic, respectively (choose a specific SEQ ID NO for Groups I, II, VI, VII or VIII, and in addition if Group III is chosen, choose a specific MHC molecule (i.e., a specific SEQ ID NO for one of Groups I, II, VI or VII, a specific SEQ ID NO/a specific MHC molecule for Group III) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These peptides/derivatives, mimetics, complexes, antibodies and T cells are distinct because their structures are different (Groups I, II, III) or they recognize different peptides (Groups VI and VII).

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8. If Applicant elects the Invention of Group IV or V, Applicant is further required to (1) elect a specific method using a specific peptide/derivative or a specific peptide mimetic (i.e., a specific SEQ ID NO) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These peptides/derivatives or mimetics are distinct because their structures are different.

- 9. Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.
- 10. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.
- 11. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).
- 12. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.
- 13. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.
- 14. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

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15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne DiBrino whose telephone number is (703) 308-0061. The examiner can normally be reached Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Marianne DiBrino, Ph.D.

Patent Examiner

Group 1640

Technology Center 1600

September 29, 2000

CHRISTINA Y. CHAN
SUPERVISORY PATENT EXAMINER
GROUP 1800 / 6 (4)